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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,821	09/07/2004	Anees Abdulquadar Karnachi	PA/4-32394A	8908

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,821	KARNACHI ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the receipt of applicant's arguments dated 12/19/07.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-31 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 11/639172. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite a pharmaceutical for treating a cyclooxgenase-2 dependent disorder comprising –methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid, with residual moisture of 1.5% to 5%. Independent claim 1 of '172 recites the same compound for the same disorders treatment, the only difference is the dosage of the compound in the composition which would be obvious to one of ordinary skill in the art to change according to patients needs and severity of the disease. The limitations in independent claims of application '172 are the same as the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/231438. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a pharmaceutical for treating a cyclooxgenase-2 dependent disorder comprising –methyl-2-(2'-chloro-6'-fluoroanilino)phenylacetic acid, with residual moisture of 1.5% to 5%. Independent claim 1 of '438 recites the same compound for the same disorders treatment, the only difference is the amount percentage of the compound recited in '438 in the composition which would be obvious to one of ordinary skill in the art to optimize the amount of the compound as a routine practice. The limitations in the dependent clams of '438 are also encompassed in the scope of instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al. WO 99/11605 (Fujimoto).

Fujimoto teaches 2-alkyl-2-arylaminophenylacetic acids of formula I where if R=methyl R1 is chlorine R2-R4 is hydrogen and R5 is fluorine it would satisfy applicants limitation of using

5-methyl-2-(2'chloro-6'-flouroanilino)phenylacetic acid for the treatment of cyclooxygenase-2 mediated diseases (abstract, claims and table 1). The Cox-2 inhibitors of formula I could be formulated into a tablet comprising the active ingredient of 2-alkyl-2-arylaminophenylacetic acid along with lactose, cellulose, sodium carboxymethylcellulose (croscarmelose sodium) and polyvinylpryrrolidone (povidone), the amount of active ingredient is within the applicants specified range depending on the weight of the patient, for instance 4mg/Kg is 400 mg for a patient that weighs 100 Kg. See claims, page 19 3rd paragraph, page 6 paragraph 2. Regarding the limitation of residual moisture levels within a certain range is met, because it is inherent that any tablet formulation will naturally have a small amount of moisture associated with the methodology to make it, for instance the normal moisture uptake of the ingredient especially hydrophilic ingredients could give the tablet a residual moisture content as clamed, the burden is shifted to the applicants to show that their tablets would not contain the same amount of moisture as the tablets encompassed within WO 99/11605. The limitation in claim 21 that the dried granulation contains microcrystalline cellulose is met since Fujimoto teaches that the tablets can be comprised of cellulose, it is inherent that the two compounds are the same, just because the crystals are microcrystalline does not mean that it would behave differently when granulated into a tablet, the same compound will have the same properties and desired effect when pressed into a tablet formulation. The limitation in claim 21 that the dried granulation contains lactose monohydrate is met since it is inherent that lactose can comprise lactose monohydrate because it is simply one lactose molecule coordinated through nonbonding interaction with 1 molecule of water, it is inherent that some water molecules from the surrounding environment would interact with lactose to form lactose monohydrate, the burden is shifted to the applicants to show that lactose within the tablet in WO 99/11605 would not form at least one molecule of lactose monohydrate.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/11605 in view of Hancock et al US 6,063,811 (Hancock).

Fujimoto is disclosed above. The Fujimoto patent is silent on whether the cellulose used in the tablet formulation is microcrystalline and if the lactose can comprise lactose monohydrate.

The Hancock patent is used to show that the use of microcrystalline cellulose, lactose monohydrate and croscarmellose sodium in tablet formulations for the treatment of cyclooxygenase-2 mediated diseases by NSAID's were well known in the art at the time of the invention (col. 2 lines 8-15 and examples).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Fujimoto discloses all of the current applications claimed invention but is silent on whether the cellulose used in the tablet formulation is microcrystalline and if the lactose can comprise lactose

monohydrate, while the Hancock patent is used to show that the use of microcrystalline cellulose, lactose monohydrate and croscarmellose sodium in tablet formulations for the treatment of cyclooxygenase-2 by NSAID's were well known in the art at the time of the invention. The motivation to combine the above documents would be a tablet comprising 5-methyl-2-(2'chloro-6'-flouroanilino) phenylacetic acid, povidone, microcrystalline cellulose, lactose monohydrate and croscarmellose sodium for the treatment of cyclooxygenase-2 mediated diseases. Thus, the claimed invention, as a whole was prima facie obvious over the combined teachings of the prior art.

Response to Arguments

1. Applicant's arguments filed 12/19/07 have been fully considered but they are not persuasive. Applicant argues that:

- Fujimoto at least does not teach any residual moisture level of the compositions therein.

In fact, Fujimoto does not teach or exemplify any specific formulations for pharmaceutical compositions. Although compositions within the scope of Fujimoto might be prepared with the recited residual moisture levels, such residual moisture levels are not a characteristic that necessarily flows from the teachings of Fujimoto. As such, the Action provided no basis to reasonably support any determination that the recited residual moisture levels of applicant's claimed inventions are an inherent characteristic of Fujimoto. Applicants respectfully submit that the present claims are thus patentable over Fujimoto at least for the above reason.

To respond: this argument is not persuasive because Fujimoto teaches 2-alkyl-2-arylaminophenylacetic acids of formula I wherein if R=methyl R1 is chlorine R2-R4 is hydrogen and R5 is fluorine and thus it would satisfy applicants limitation of using 5-methyl-2-(2'chloro-6'-flouroanilino)phenylacetic acid for the treatment of cycloooxygenase-2 mediated diseases. Same compositions must have the same affects. Accordingly, Fujimoto teaches the same

composition for the same population wherein residual moisture comprised is not an intended component of the composition. therefore, the normal moisture uptake of the ingredient especially hydrophilic ingredients could give the tablet a residual moisture content as claimed, the burden was shifted to the applicants to show that their tablets would not contain the same amount of moisture as the tablets encompassed within WO 99/11605, however, applicant's arguments has now shown any explanation why WO 99/11605 would not have the same residual moisture.

- Fujimoto, in contrast, does not expressly or inherently teach or suggest any particular residual moisture level. Hancock:, like Fujimoto, also contains no teaching or suggestion of any particular residual moisture level in the compositions disclosed therein. As both Fujimoto and Hancock lack any disclosure regarding residual moisture levels, the combination of Fujimoto and Hancock cannot produce any composition, method or granulation of the presently claimed invention.

To respond: in addition to the discussion above, it is noted that the normal moisture uptake of the ingredient especially hydrophilic ingredients could give the tablet a residual moisture content as claimed. A compound and its properties are not separable, the prior art clearly administers same ingredient to same patients. It is not necessarily that the prior art discloses each and every residual component that a composition may have since it is not an intended ingredient. The Hancock patent is used to show that the use of microcrystalline cellulose, lactose monohydrate and croscarmellose sodium in tablet formulations for the treatment of cyclooxygenase-2 mediated diseases by NSAID's were well known in the art at the time of the invention (col. 2 lines 8-15 and examples).

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618